

### REMARKS

Claims 1-5, 7-27, 28, 40, 42-44 and 47 have been canceled without prejudice or disclaimer. Claims 48-79 have been added and therefore are pending in the present application. Claims 48-79 are supported by claims 1-47 and are drawn to the elected subject matter.

The specification has been amended to correct an obvious error. Specifically, the amino acid identified as "D" at position 42 has been corrected to "L", as supported by the sequence listing, Example 1 (page 64, line 25) and Figure 1. Applicants therefore submit that no new matter is added.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

#### I. The Restriction Requirement

The Office Action made a restriction requirement. As provided therein, Applicants provisionally elected with traverse the invention of clauses (b), (e) and (f) recited in claim 1. Applicants confirm this election. Applicants reserve the right to file continuing applications directed to non-elected subject matter.

#### II. The Rejection of Claims 1, 2, 5, 7-9, 11-15, 25 and 26 under 35 U.S.C. 101

Claims 1, 2, 5, 7-9, 11-15, 25 and 26 are rejected under 35 U.S.C. 101 as directed to non-statutory subject matter. This rejection is respectfully traversed.

The claims are drawn to subtilase variants, i.e., subtilisins that have been modified by an insertion of one or more amino acids. Thus, adding a limitation such as "isolated and modified" is not required.

However, in order to advance prosecution, the claims have been rewritten to recite "modified subtilisases". This amendment does not change the scope of the claims.

#### III. The Rejection of Claims 1, 2, 5, 7-9, 11-15, 25, 26, 38, 40, 42-44 and 47 under 35 U.S.C. 112

Claims 1, 2, 5, 7-9, 11-15, 25, 26, 38, 40, 42-44 and 47 are rejected under 35 U.S.C. 112 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

It is well settled that "[t]he first paragraph of section 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance." *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). Moreover, "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 169 USPQ at 369.

It is also well settled that "[t]he test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter...." *In re Kaslow*, 217 USPQ 1089, 1096 (Fed. Cir. 1983).

As set forth in Federal Circuit decisions, a specification complies with the written description requirement if it provides "a precise definition, such as by structure, formula, chemical name, or physical properties of the claimed subject matter sufficient to distinguish it from other materials." See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002).

Applicants submit that the specification complies with the written description requirement.

The claims are drawn to subtilisin variants comprising an insertion of one or more amino acids at one or more specified positions. The amino acid sequences of subtilisins are well known in the art. Thus, one of ordinary skill in the art is able to envision the structure of the claimed subtilisin variants comprising an insertion of one or more amino acids. Based on Applicants' disclosure, one of ordinary skill in the art would expect that subtilisins comprising an insertion of two or more amino acids at the specified positions would function as proteases.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **IV. The Rejection of Claims 1, 2, 5, 7-9, 11-15, 25, 26, 38, 40, 42-44, and 47 under 35 U.S.C. 112**

Claims 1, 2, 5, 7-9, 11-15, 25, 26, 38, 40, 42-44, and 47 are rejected under 35 U.S.C. 112 as being indefinite. Specifically, the Office states "Claim 1 is indefinite because it fails to clearly identify the basis for numbering amino acid positions in the amino acid sequence of a generic

subtilase where the elected amino acid insertions are to be made...." This rejection is respectfully traversed.

The claims recite that the recited positions correspond to the positions of subtilisin BPN'. Furthermore, the specification discloses that the amino acid sequence of subtilisin BPN' is set forth in SEQ ID NO: 7. Therefore, it is unnecessary to insert the sequence identifier in the claims.

However, in order to advance prosecution, the claims have been rewritten to recite that the numbering is according to the amino acid sequence of subtilisin BPN' of SEQ ID NO: 7. This amendment also does not change the scope of the claims.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### V. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,



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Date: January 30, 2004